GENERAL GUIDELINES FOR THE SUBMISSION OF BIOTHREAT SPECIMENS

Louisiana Office of Public Health Central Laboratory 325 Loyola Avenue, 7th and 8th Floors New Orleans LA 70112

GENERAL GUIDELINES FOR THE SUBMISSION OF BIOTHREAT SPECIMENS

APPROVALS PAGE

SIGNATURES:					
Henry B. Bradford, Ph.D. Public Health Laboratory Director					
Stephen J. Martin, Ph.D. Public Health Laboratory Assistant Director					
Arthur F. Hagar, Ph.D. Public Health Laboratory Assistant Director					
Ashim K. Gupta, Ph.D. Laboratory Safety Officer					

TABLE OF CONTENTS

INTRODUCTION	9
PURPOSE	9
POLICY	9
TYPES OF ANALYSIS	.10
REPORTING TIME	.10
LABORATORY FORMS	10
UNACCEPTABLE/UNSATISFACTORY SPECIMENS	.11
CONDITIONAL ACCEPTANCE	.11
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – BACILLUS ANTHRACIS	.12
PURPOSE.	.12
POLICY	.12
SPECIMEN COLLECTION, HANDLING, AND STORAGE	.12
PROCEDURE	.13
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – BRUCELLA SPECIES	.14
PURPOSE	.14
POLICY	.14
SPECIMEN COLLECTION, HANDLING, AND STORAGE	.14
SPECIAL SAFETY PRECAUTIONS	15
PROCEDURE	15
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – BURKHOLDERIA MALLEI	
PURPOSE	.16

POLICY	16
SPECIMEN COLLECTION, HANDLING, AND STORAGE	16
PROCEDURE	16
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – BURKHOLDERI PSEUDOMALLEI.	
PURPOSE	18
POLICY	18
SPECIMEN COLLECTION, HANDLING, AND STORAGE	18
PROCEDURE	19
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – CLOSTRIDIUM BOTULINUM/BOTULINUM TOXIN	
PURPOSE	20
POLICY	20
SPECIMEN COLLECTION, HANDLING, AND STORAGE	20
PROCEDURE	20
FURTHER IDENTIFICATION – COXIELLA BURNETII	22
PURPOSE	22
POLICY	22
SPECIMEN COLLECTION, HANDLING, AND STORAGE	22
PROCEDURE	23
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – FRANCISELLA TULARENSIS.	24
PURPOSE	24
POLICY	24

SPECIMEN COLLECTION, HANDLING, AND STORAGE	24
PROCEDURE	25
FURTHER IDENTIFICATION – POXVIRUS (VARICELLA-ZOSTER, VACC ORTHOPOX VIRUS)	
PURPOSE	26
POLICY	26
SPECIMEN COLLECTION, HANDLING, AND STORAGE	26
PROCEDURE	27
FURTHER IDENTIFICATION – SARS CORONAVIRUS	29
PURPOSE	29
POLICY	29
SPECIMEN COLLECTION, HANDLING, AND STORAGE	29
PROCEDURE	30
FURTHER IDENTIFICATION – VIRAL HEMORRHAGIC FEVERS (VHFs)	31
PURPOSE	31
POLICY	31
SPECIMEN COLLECTION, HANDLING, AND STORAGE	31
PROCEDURE	32
CULTURE CONFIRMATION-FURTHER IDENTIFICATION – YERSINIA PESTIS.	34
PURPOSE	34
POLICY	34
SPECIMEN COLLECTION, HANDLING, AND STORAGE	34

PROCEDURE	34
ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – GENERAL CRITERIA	36
PURPOSE	36
POLICY	36
SPECIMEN COLLECTION, HANDLING, AND STORAGE	36
ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – BACILLUS ANTHRACIS	38
PURPOSE	38
POLICY	38
SPECIMEN COLLECTION, HANDLING, AND STORAGE	38
PROCEDURE	38
ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – <i>BR</i> SPECIES	
PURPOSE	39
POLICY	39
SPECIMEN COLLECTION, HANDLING, AND STORAGE	39
PROCEDURE	39
ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – <i>CL BOTULINUM</i>	
PURPOSE	40
POLICY	40
SPECIMEN COLLECTION, HANDLING, AND STORAGE	40
PROCEDURE	40

ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – FRANCISELLA TULARENSIS
PURPOSE42
POLICY42
SPECIMEN COLLECTION, HANDLING, AND STORAGE42
PROCEDURE42
ANALYSIS OF FOOD SUSPECTED IN FOODBORNE ILLNESS – YERSINIA PESTIS
PURPOSE43
POLICY43
SPECIMEN COLLECTION, HANDLING, AND STORAGE43
PROCEDURE43
ANALYSIS OF ENVIRONMENTAL SAMPLES – SELECT BT AGENTS44
PURPOSE44
POLICY44
SPECIMEN COLLECTION, HANDLING, AND STORAGE44
PROCEDURE45

APPENDIX 1 – LAB FORM 93 (BACTERIOLOGY LAB FORM)46
APPENDIX 2 – LAB FORM 47 (FOOD AND DRUG FORM)47
APPENDIX 3 – LAB FORM 96 (IMMUNOLOGY LAB FORM)48
APPENDIX 4a – LABORATORY RESPONSE NETWORK RECEIPT FOR PROPERTY RECEIVED/RETURNED
APPENDIX 4b – LA OFFICE OF STATE POLICE AND LA DHH OPH OFFICIAL COMPLAINT/OFFENSE REPORT50
APPENDIX 4c – LA DHH OPH CONSENT FORM – DISPOSAL OF BIOTERRORISM SAMPLES52
APPENDIX 5 – FAX REQUEST FOR SPECIMEN SHIPPING SUPPLIES53
APPENDIX 6 – CDC FORM 5054
APPENDIX 7 – CDC CONSENT FORM: SARS-COV REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TESTING56
APPENDIX 8 – CDC CONSENT FORM: SARS-COV EIA TESTING60
APPENDIX 9 – LABORATORY PROCEDURES FOR PACKAGING AND SHIPPING INFECTIOUS SUBSTANCES AND BIOLOGICAL AGENTS64
APPENDIX 10 – LABORATORY RESPONSE NETWORK CHAIN OF CUSTODY

INTRODUCTION

Purpose

These guidelines are intended for hospital clinical laboratories, sanitarians, safety officers, and all other agencies that submit potential biothreat specimens to the Louisiana Office of Public Health (LA OPH) Central Laboratory for confirmation/identification. This document provides specific recommendations for specimen selection, collection and transport of microbial and viral biothreat specimens. A satisfactory specimen is essential for valid laboratory test results. In order to obtain a valid specimen, it is important to closely adhere to the specific recommendations and requirements listed pertaining to your type of sample.

Policy

Contact Information- For additional information or inquiries about special isolates not found in this section, contact the appropriate person or lab for consultation with the Laboratory Manager or Laboratory Supervisor.

Location	Unit	Contact Person	Position	Phone Number	Fax Number
Central Lab New Orleans		Henry B. Bradford, Jr., PhD	Laboratory Director	504-568-5375	504-568-5393
Central Lab New Orleans		Stephen J. Martin, PhD	Assistant Laboratory Director	504-568-5378	504-568-5393
Central Lab New Orleans		Arthur Hagar, PhD	Assistant Laboratory Director	504-568-2545	504-568-5393
Central Lab New Orleans		Kerri Gerage	Bioterrorism Coordinator	504-568-8102	504-568-5393
Central Lab New Orleans		Keri Beeson	Bioterrorism Program Advisor	504-568-2479	504-568-5393
Central Lab New Orleans	Microbiology	Wayne Dupree	Microbiology Manager	504-568-3453	504-568-5393
Central Lab New Orleans	Virology / Immunology	Gita Talati	Virology/ Immunology Manager	504-568-5374	504-568-8058
Central Lab New Orleans	Molecular Bacteriology	Danielle Haydel	Molecular Bacteriology Supervisor	504-568-2373	504-568-5393
Central Lab New Orleans	Virology / Immunology	DeNeen Grant	Virology/Immunology Supervisor	504-568-4039	504-568-8058
Central Lab New Orleans	General Bacteriology	Lori Kravet	General Bacteriology Supervisor	504-568-7683	504-568-5393
Regional Lab Lake Charles		Michael Purpera	Laboratory Manager	337-475-8040	
Regional Lab Shreveport		Jim Gilbert	Laboratory Manager	318-221-0859	
Central Lab New Orleans		24 Hour Contact		877-309-2867	

Types of Analysis

The Louisiana Office of Public Health Division of Laboratory Services provides three general types of analysis for Microbial and Viral Biothreat specimens:

- 1. Culture Confirmation/Further Identification of Selected Biothreat Agents
- 2. Analysis of Environmental Specimens Suspected in Biowarfare
- 3. Analysis of Food Suspected in Foodborne illness associated with Agents of Bioterrorism

Reporting Time

- 1. **Rapid Test Results** for cultures or environmental specimens can be obtained in 4-6 hours using rapid testing methods. All specimens for subsequent testing by rapid methods will be accepted by the OPH Central Laboratory if requested by the Infectious Disease Epidemiology Section.
- 2. **Clinical Isolation** for bacteriology may require from 5-10 days for isolation and an additional 2-7 days for identification.
- 3. **Culture Confirmation** for bacteriology may require 2-7 days for identification. Isolates that need to be forwarded to CDC for confirmation will take longer. Presumptive results can be obtained in 4-6 hours using rapid testing methods.
- 4. **Further Identification** for virology/immunology may require 1-2 days for identification. Specimens that need to be forwarded to CDC for confirmation will take longer. Presumptive results can be obtained in 4-6 hours using rapid testing methods.
- 5. **Food Analysis** for bacteriology may require from 5-10 days for isolation and an additional 2-7 days for identification. Presumptive results can be obtained in 4-6 hours using rapid testing methods.
- 6. **Environmental Analysis** for Biothreat agents may require from 5-10 days for isolation and an additional 2-7 days for identification. Reporting time for Biothreat Agents will depend on the test requested and the organism suspected. Presumptive results can be obtained in 4-6 hours using rapid testing methods.

Laboratory Forms

Lab forms are legal documents. If information is to be handwritten, please write legibly. Write firmly on a hard smooth surface so that all copies are legible. Fill in all of the required available information. Please contact the appropriate laboratory to request forms.

- Lab Form 93 Bacteriology Lab Form To be completed for all Clinical Isolation and Culture Confirmation Bacteriology samples (see Appendix 1 for sample form)
- 2. Lab Form 47 Food and Drug Form To be completed for all Food Analysis (see Appendix 2 for sample form)
- 3. Lab Form 96 Immunology Lab Form To be completed for all Further Identification Virology/Immunology specimens (see Appendix 3 for sample form)

4. Laboratory Response Network Forms – To be completed for all possible Biothreat Environmental Bacteriology samples (see Appendices 4a, 4b, 4c for sample forms)

Unacceptable/Unsatisfactory Specimens

A specimen will be considered unacceptable/unsatisfactory if it arrives at the laboratory without the appropriate data form or on expired or incorrect media. Should this occur, the submitting agency will be contacted and might be asked to resubmit the specimen. To determine if additional criteria apply to a given specimen, refer to the specific section detailing the specimen type or test in question.

Conditional Acceptance

Under certain circumstances, the laboratory may consider a compromised specimen conditionally acceptable. In these cases, the results will be reported to the submitter with a qualifier identifying the precise conditions, reasons, concerns or situations impacting the results as reported. Circumstances under which a specimen is conditionally analyzed include but are not limited to:

- 1. Special request and written authorization by the submitter to perform analysis.
- 2. There is mutual agreement to analyze the specimen following consultation between the health care provider and the State Epidemiologist and/or the Office of Public Health Laboratory Director or his designee.
- 3. A duplicate specimen is not available and the specimen cannot be recollected.
- 4. The adverse specimen condition is known not to interfere with the analysis requested.
- 5. There is insufficient specimen quantity to perform a confirmation or repeat analysis of an initial or preliminary finding.
- 6. There are questionable factors about the collection, processing, handling, and transport of a specimen that may impact the final results.
- 7. The results can be reported with a reduced degree of confidence that is authorized as acceptable to the health care provider or sufficient for the intended purpose of the test.
- 8. Professional scientific judgment by the State Epidemiologist and/or the Office of Public Health Laboratory Director or his designee.